

REMARKS

In the Office Action mailed March 9, 2004, material referring to ultrasound measuring of skeletal age disclosed but not claimed in US Patent Publication 2002/0162031 to Levin et al. is used as prior art in rejections of claims in the present application. Applicants assert that the subject matter claimed in the present application was invented prior to the effective date of the publication and that in accordance with MPEP 715 the rejections should be withdrawn. An affidavit under 37 CFR §1.131 made by an inventor of the present application swearing back of the publication is attached herewith. Under the assumption that the rejections based on the publication will be removed, the publication it is not referred to in the discussion of the claim rejections below.

Claims 1-25, 27-29, 36-38, 40, 46, and 62 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,468,215 to Sarvazyan et al.

Claim 1 claims using acoustic energy that is propagated substantially transverse to a skeletal structure to determine the structure's age. The Examiner contends that "Sarvazyan et al uses both longitudinal and flexural components of bone measurements to assess skeletal age. Col. 7 lines 22-40 defines the flexural portion as through the bone." and that therefore Sarvazyan et al teaches using acoustic energy propagated transverse to bone to determine bone age. Applicants respectfully traverse the Examiner's contention.

Longitudinal sound waves refer to sound waves in which *compressive strain* of a medium propagates through the medium. Flexural sound waves refer to sound waves in which *shear strain* of a medium propagates through the medium and are often referred to as *transverse waves not because of a direction of propagation*, but because motion of mass points in the medium is substantially transverse to the direction of propagation of the waves. Neither of the terms "longitudinal" or "flexural" indicates by itself a direction along which waves propagate and Column 7 lines 22-40 do not appear to define a direction of propagation of flexural waves relative to bone.

In addition, not only do the lines not appear to explicitly define a direction of propagation of flexural waves through bone, *they in fact imply that the direction of propagation is along the bone and not through or transverse to the bone*. The lines note that the flexural wave velocity is a function of, and can be used to determine, cortical thickness of bone. However, this is true of flexural waves *that propagate along the bone and not flexural waves that propagate through the bone*. Flexural waves that propagate transverse to the bone “see”, in effect, an infinite extent of bone in a direction perpendicular to the direction of propagation of the waves and *are therefore not in general useable to determine cortical thickness of bone*. The fact that the flexural waves are being used to determine cortical thickness therefore implies that the flexural waves referred to by Sarvazyan propagate, as do the longitudinal waves, along the bone and not transverse to the bone. A supposition that the flexural waves refer to waves propagating transverse to bone is therefore antithetical to the teachings of Sarvazyan et al.

Irrespective of the definition of flexural sound waves, applicants submit that Sarvazyan et al. teaches away from using flexural sound waves for determining bone age. Column 3 lines 46-50 specifically cite longitudinal waves as useable to determine skeletal age. Nowhere does the patent note that flexural waves may be used for determining skeletal age. The citation of longitudinal waves and the omission of a similar citation with respect to flexural waves, teaches away from using flexural waves for determining skeletal age.

In view of the above it must be concluded that Sarvazyan et al. cannot be used to support either an anticipation rejection or a prima facie obviousness rejection of claim 1.

The Examiner cites in rejecting claim 1, presumably under 35 U.S.C. §103, that “in the alternative”, column 1 of US 5,895,364 to Donskoy teaches “that flexural measurements mean across or transverse to bone and longitudinal means along bone”. Applicants respectfully traverse the rejection.

Donskoy, teaches, as noted in the patent on column 2 line 45, a “subsonic technique ... for the quantitative measurement of bone quality and the diagnosis of osteoporosis.” Subsonic means, “less than the speed of sound in a medium”. Donskoy therefore does not relate to the propagation of sound in bone and without an explanation

as to how characteristics of Donskoy's subsonic techniques relate to characteristics of sonic techniques, Donskoy et al does not support a prima facie rejection of claim 1. Furthermore, applicants could not find where in column 1 Donskoy et al teaches "that flexural measurements mean across or transverse to bone" and respectfully request that the Examiner indicate which lines in column 1 promulgate the teaching.

The Examiner further argues that US 5,806,520 to "Berger et al is directed to measurement of skeletal maturation in neonates using transverse through-transmission with opposed transducer faces, see Col. 2 lines 11-22, whereupon it would have been obvious to adapt same for long bone scanning in Sarvazyan et al in order to accurately know the exact path distance which the ultrasound takes via this caliper style transducer separation setting." Applicants respectfully traverse.

Sarvazyan et al, by providing bone measurements along the bone probes the characteristics of the cortical region of a bone. In transverse measurements, such as those described in Berger et al, sound waves travel not only through cortical bone but also through trabecular bone. As a result, transverse measurements provide information different from that of measurements along bone and it is not obvious to use or adapt the methods of one to provide the different information that the other provides. Furthermore, Berger et al recite using their methods for skeletal maturation in neonates, not in the context of bone age, but in the context of a "degree of mineralization of the skeleton in particular in order to follow the evolution of the bone architecture or of the elasticity of the bone structure" (column 9 line 59-64). It is noted that a neonate is a newborn up to the age of 4 weeks. None of the cited documents provide motivation or indicate how to extrapolate a method specifically limited to measuring degree bone mineralization of a newborn over a period of 4 weeks to a method of determining bone age.

Finally, Sarvazyan et al's apparatus, since it constrains the path of ultrasound to extend between two well defined points on the skin of the patient along the bone and measures thickness of soft tissue using reflected ultrasound, provides an accurately defined path for ultrasound along bone. The patent notes (column 5 lines 10-19) that the apparatus effectively eliminates contribution of the soft tissue to its ultrasound measurements by measuring the thickness of soft tissue. The patent must therefore be understood to teach a satisfactory method for providing an accurate propagation path for

ultrasound in bone and to reject a need or motivation for using additional methods to provide such a path. In addition, Berger et al uses a method for correcting for soft tissue in determining a bone propagation path for ultrasound similar to that already promulgated in Sarvazyan et al, *i.e.* reflecting ultrasound from the surface of bone (column 7 line 60 - column 8 line 4) to determine soft tissue thickness. It therefore appears in this respect that even if there were motive for providing a method for improving measurement of bone propagation path, Berger et al would not be the source for such a method.

In view of the above, applicants submit that it is inappropriate to combine Berger et al with Sarvazyan et al to provide a *prima facie* case for an obviousness rejection of claim 1.

Independent claim 49 is rejected under 35. U.S.C. §103(a) as being unpatentable over Sarvazyan et al in view of Berger et al. Applicants submit that claim 49 is patentable over the cited references for the same reasons that claim 1 is patentable over the references.

Independent claim 62 is rejected as being anticipated by Sarvazyan et al and obvious over Sarvazyan et al in view of Donskoy or Berger et al. Applicants submit that the claim is patentable over the cited art for the same reasons that claim 1 is patentable over the art.

Independent claim 63 is rejected as obvious over Savazyan et al in view of Antich et al (US 5,197,475). The Examiner states that it would have been obvious in view of Antich et al "to form ratios of through-bone velocities in order to characterize a bone integrity, understood by Berger et al to include skeletal maturing akin to parameters such as assessed in Antich et al". Applicants respectfully traverse.

Claim 63 claims determining bone age using a ratio between an acoustic velocity along a length of a bone and an acoustic velocity through the bone in a direction transverse to the bone. None of the cited references uses, or even mentions, a ratio between an acoustic velocity for waves traveling along a bone and acoustic velocity for waves traveling through the bone, transverse to the bone. They cannot be combined to provide the invention claimed in claim 62 and therefore cannot support a *prima facie* case of obviousness against the claim.

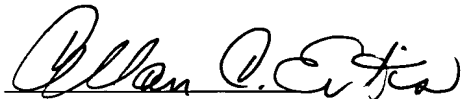
Applicants respectfully point out that a First Supplementary Information

Disclosure Statement was filed on January 27, 2003 (including a 2-page PTO-1449 form) and a Second Supplementary Information Disclosure Statement was filed on June 23, 2003 (including a 1-page PTO-1449 form). In the Office Action dated March 9, 2004, the Examiner returned PTO-1449 forms without initialing pages labeled 5 and 6. Applicants are resubmitting the PTO-1449 forms and respectfully request that the items listed thereon be initialed by the Examiner to ensure that they appear on the face of the patent that may issue on the present application. Applicants assume that the art has already been considered by the Examiner in accordance with MPEP §609.

Applicants bring to the Examiner's attention that they could not obtain a copy of "McKERN, et al.; "Skeletal Age Changes in Young American Males;" Tech Rep. EP 45. Environmental Protection Research Div. Natick, MA", cited in the specification of the present application (on page 22, lines 24-26), despite efforts made to obtain it. Applicants believe that the reference is only of background relevance and attach page 433 of "Gray's Anatomy" 38th Edition where the article is referred to.

In view of the above, applicants submit that all the independent claims in the present application are patentable and that dependent claims in the application are patentable either through patentable material that they contain or through dependence on the independent claims. An action on the merits is respectfully awaited.

Respectfully submitted,
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